

Appl. No. 10/753,669  
Docket No. 7537CQ  
Amdt. dated July 30, 2007  
Reply to Office Action mailed on May 7, 2007  
Customer No. 27752

## REMARKS

### Claim Status

Claims 1 – 11 and 13 – 52 are pending in the present application. No additional claims fee is believed to be due.

Claims 1 and 40 have been amended to include the feature of a transducer adapted to receive a signal from the bio-recognition element and provide an output in response to the received signal. Support for this amendment can be found on page 15, lines 2 – 9 of the Specification.

Claim 9 has been amended to depend from claim 8.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

### Rejection Under 35 USC §103(a) Over Everhart In View of Al-Sabah and Eppstein

Claims 1 – 11 and 15 – 52 have been rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 5,468,236 to Everhart (hereinafter “Everhart”) in view of U.S. Pat. No. 5,868,723 to Al-Sabah (hereinafter “Al-Sabah”) and U.S. Pat. No. 5,458,140 to Eppstein (hereinafter “Eppstein”). Applicants respectfully traverse the rejection. In addition, Applicants note that claims 13 – 14 have not been rejected in the Office Action, however, Applicants will address the Office Action as though these claims stand rejected. If claims 13 – 14 are allowable, Applicants respectfully request an indication of allowable subject matter in the next Office Action.

It is well established that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must

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be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP §2143).

The Office Action states, correctly, that Everhart does not specifically disclose a sensor capable of detecting a low level of analyte. (The Office Action, page 3, bottom). The Office Action goes on to state

However, Everhart teaches a chemically reactive substance acting upon mammalian bodily excrement that provides the types of substance present and an estimate of the concentration of the substance (Everhart col. 3, lines 21 – 29). Everhart additionally teaches the minimum amount is simply that amount which is necessary to activate the chemically reactive means and this minimum amount is in part dependent upon the concentration in the mammalian bodily excrement of the specific substance of interest. Everhart further teaches this minimum threshold level is readily determined by one of ordinary skill in the art with routine experimentation. (Everhart, col. 4, lines 3 – 19).

(The Office Action, page 4). However, Applicants point out that Everhart also discloses that “[a]s with many analytical procedures, there generally will be a minimum threshold level for many of the chemically reactive means which come within the scope of the present invention.” (Everhart, col. 4, lines 8 – 11) (emphasis added). Thus, it is Applicants’ position that while Everhart may disclose that determining the threshold level for the chemically reactive means requires routine experimentation by one of ordinary skill in the art, there is still no teaching or suggestion of a biosensor being adapted to detect a target biological analyte present at a low concentration in bodily waste or on the wearer’s skin, as is recited in claim 1 of the present application.

In support of Applicants’ position, the present specification discloses “[c]hemical sensors, on the other hand, which rely on chemically reactive means, generally do not have either the high selectivity or the amplification properties of biosensors and, therefore, are not well suited to detect biologically reactive analytes . . . .” (The present application, page 12, lines 30 – 34). Therefore, Applicants submit that even if one of ordinary skill in the art determined the minimum threshold for the chemically reactive means of Everhart, there is still no teaching or suggestion that such determination would provide a suitable level of detection for the biosensor recited in claim 1 of the present application. Additionally, neither Al-Sadah or Eppstein overcome the failings of Everhart.

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The Office Action looks to Al-Sadah for a teaching or suggestion of an actuator. As best understood by Applicants, Al-Sadah is directed to an apparatus for detecting and indicating moisture (i.e., water content) in a garment such as a diaper, training pant or adult undergarment. (Al-Sadah, abstract). Claim 15 of the present application recites, *inter alia*, wherein the biosensor provides a signal to at least one of the group of: the wearer, a caretaker, an actuator. Claim 28 of the present application recites, *inter alia*, an actuator that performs a responsive function when the biosensor detects a target biological analyte. Applicants respectfully remind the Office that a biosensor in the present application refers to a component comprising one or more biologically reactive means being adapted to detect one or more target pathogenic microorganisms or related biomolecules, additionally having the capability to provide a signal of the detection to wearer, caretaker, or an actuator. (The present application, page 12, lines 20 – 25). Thus, Applicants submit that the moisture detector in Al-Sabah does not amount to a teaching or suggestion of the actuator recited in claim 15 or claim 28 of the present application, as there is no teaching or suggestion of an actuator capable of receiving a signal from a biosensor.

The Office Action states “Everhart/Al-Sabah does not disclose a transducer capable of detecting a target analyte. Eppstein . . . discloses a transducer to selectively direct analyte withdrawal to [a] collection reservoir or absorbent patch (Eppstein col. 5, lines 21 – 25). (The Office Action, page 5, top). Applicants respectfully disagree with the Office’s reading of Eppstein.

As best understood by Applicants, Eppstein is directed to a method of enhancing the permeability of the skin or mucosa to an analyte for diagnostic purposes by utilizing ultrasound or ultrasound plus a chemical enhancer. (Eppstein, abstract). Eppstein discloses modulating the frequency of ultrasonic energy fields produced by one or more ultrasonic transducers (i.e., devices capable of producing ultrasonic fields) to increase the flux of a drug or analyte across the skin. (Eppstein, col. 9, lines 34 – 54; col. 10, lines 22 – 24). The portion of Eppstein cited by the Office Action (i.e., col. 5, lines 21 – 25) discloses the use of ultrasonic transducers to selectively direct analyte withdrawal from the body. However, this particular portion of Eppstein further discloses a method for

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accomplishing the withdrawal, namely that “[t]ransducers may be placed on either side of a fold of flesh, such as an ear lobe, or in a pattern on a single dermal or mucosal surface and be selectively energized . . . to control transdermal flux in the desired direction and at the desired rate. (Eppstein, col. 5, lines 24 – 31).

Claim 1 recites, *inter alia*, a transducer adapted to receive a signal from a bio-recognition element and provide an output in response to the received signal. Thus, Applicants submit that Eppstein does not provide any teaching or suggestion of the transducer recited in claim 1 of the present application, as there is no teaching or suggestion in Eppstein of a transducer receiving a signal from a bio-recognition element and providing an output in response to the received signal.

The Office Action states “Everhart discloses the target analyte may include a health or nutritional marker . . . which may be an enzyme, endogenous secretion, proteinaceous matter, or microorganism (col. 3, lines 56 – 65).” (The Office Action, page 3). Looking to the cited portion of Everhart, i.e. col. 3, lines 56 – 65, Applicants are unable to find any disclosure of the “substance” of Everhart including microorganisms. Therefore, it is Applicants’ position that Everhart does not teach or suggest microorganisms as an example of a “substance.” In addition, Applicants are unable to find any mention in the Office Action that Al-Sadah or Eppstein include such teaching or suggestion. Therefore, in addition to the above remarks, Applicants submit that Everhart, Al-Sadah and Eppstein do not teach or suggest the detection of microorganisms, as is recited in claims 8, 9, 46, and 47.

Regarding claims 11, 15 – 20, and 26 – 35, the Office Action states “the invention of Everhart/Al-Sabah provides a visual indication of a substance upon reacting with bodily excrement. Bodily excrement, particularly perspiration, may not necessarily provide clinically observable symptoms . . . .” (The Office Action, page 5). Applicants respectfully remind the Office that the biosensor recited in claim 1 of the present application does not necessarily provide a signal when exposed to bodily excrement, but rather when the biosensor is exposed to a suitable level of one or more particular pathogenic microorganism(s) or related bio-molecule(s). (The present application, page

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12, lines 20 – 25). Thus, contrary to the assertion of the Office Action, Applicants continue to maintain that the Office Action has not properly shown that the chemically reactive means of Everhart provides a signal upon the detection of a target biological analyte present at low concentrations in bodily waste or on the wearer's skin, as is recited in claim 1 of the present application.

The Office Action states “[r]egarding claims 22 and 24, the sensor is detachable from the article (‘236 col. 6, lines 26 – 32).” (The Office Action, page 5). Applicants are unable to find any such disclosure in the cited portion of Everhart. Applicants point out that Everhart discloses that the layers to which the chemically reactive means has been applied “can be affixed by any known means, such as by an adhesive, ultrasonic bonding, sewing, and the like.” (Everhart, col. 6, lines 27 – 32) (emphasis added). Thus, Applicants submit that the chemically reactive means of Everhart, in fact, is not detachable, as is recited in claim 24 of the present application.

Applicants are unclear as to why the portion of Everhart cited above for claim 24 is relevant to support a rejection of claim 22. Applicants are unable to find any disclosure in Everhart at col. 6, lines 26 – 32 of a support element adhering to a wearer's skin, as is recited in claim 22 of the present application. Absent any other evidence or reasoning to the contrary, Applicants submit that the combination of Everhart, Al-Sadah, and Eppstein does not disclose a support element adhering to a wearer's skin, as is recited in claim 22 of the present application, and that claim 22 is allowable for at least this reason.

The Office Action states

Regarding claims 36 – 39 and 49 – 52, Everhart describes a biosensor for detecting a target analyte upon excretion of bodily fluids or waste materials. Everhart provides a response within a period of time that stays valid until the article is discarded. The response factor would have been obvious by optimizing the type of biosensor materials . . . .

(The Office Action, page 5 – page 6). Applicants respectfully disagree with the Office's interpretation of the scope of Everhart. It is well settled that a parameter must first be recognized as a results-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. (*In re Antonie*, 559 F.2d 618, 195 USPQ 6

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(CCPA 1977). The present application discloses that "Response Factor describes the ratio of the response of the biosensor when exposed to fecal test material compared to the response of the biosensor when exposed to physiological saline and is useful in assessing the sensitivity of the biosensor for biologically active analytes expected to be found preferentially in feces versus urine." (The present application, page 18, lines 16 - 21). Applicants are unclear as to what relevance the length of time in which the chemically reactive means of Everhart provides a valid signal has to the response factors recited in claims 36 - 39 and 49 - 52 of the present application. The Office Action does not point to any other particular part of Everhart, Al-Sadah or Eppstein for such disclosure. Thus, Applicants submit that the combination of Everhart, Al-Sadah, and Eppstein does not teach or suggest a response factor, as recited in claims 36 - 39 and 49 - 52.

In view of the foregoing remarks, it is Applicants' position that the combination of Everhart, Al-Sadah and Eppstein does not teach or suggest each and every element of claim 1 or claim 40, or any of the claims depending therefrom. Accordingly, Applicants respectfully request that the rejection of claims 1 - 11 and 15 - 52 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

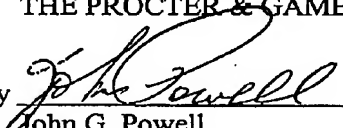
#### Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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